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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|----------------------|------------------|
| 10/786,725 | 02/25/2004 | Kirk D. Swenson | 3896-031736 (P-6004) | 2750 |
| 32182 | 7590 | 02/10/2009 | EXAMINER | |
| David W. Hight, VP & Chief IP Counsel Becton, Dickinson and Company (The Webb Firm) 1 Becton Drive, MC 110 Franklin Lakes, NJ 07414-1880 | | | TOWA, RENE T | |
| | | ART UNIT | PAPER NUMBER | |
| | | 3736 | | |
| | | MAIL DATE | | DELIVERY MODE |
| | | 02/10/2009 | | PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/786,725 | SWENSON ET AL. | |
| | Examiner | Art Unit | |
| | RENE TOWA | 3736 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 05 November 2008.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-9 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1-9 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.

4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.

5) Notice of Informal Patent Application

6) Other: _____.

DETAILED ACTION

1. This Office action is responsive to an amendment filed November 5, 2008. Claims 1-9 are pending. Claims 10-38 have been cancelled. No claim has been amended.

Claim Rejections - 35 USC § 103

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. **Claims 1-2, 5-6 & 9** are rejected under 35 U.S.C. 103(a) as obvious over Hollister (US 5,277,311) in view of Hollister (US 4,982,842).

In regards to **claims 1-2 & 9**, Hollister disclose(s) a holder assembly comprising:

a holder housing 2 for receiving a sample collection tube within a rearward end, a forward end of the holder housing 2 including;

a needle receiving port (6, 8) for receiving a needle cannula 28 therein and a safety shield 20 pivotably attached to a collar 18, said collar 18 having an opening therethrough for receiving a needle cannula 28 therethrough, the safety shield 20 is capable of being pivoted over at least a portion of a needle 12 received within the needle receiving port (6, 8) of the holder housing 2,

wherein the safety shield 20 and the collar 18 are axially rotatable with respect to the holder housing 2 about an axis of the holder housing 2, such that the safety shield 20 and the collar 18 can be radially rotated to a desired position around a needle 28 received within the needle receiving port (6, 8) and around the axis of the holder housing 2 without axial movement of the collar along the axis (see figs. 1-5; col. 3, lines 23-41);

wherein the collar 18 is annular (see figs. 1-5);

wherein the shield 20 and the collar 18 are integral and attached through a living hinge 24 (see figs. 1-5);

wherein the shield 20 comprises a rearward end, a forward end, and a longitudinal opening in the forward end for receiving a needle (see fig. 4);

wherein the collar 18 attaches to the holder housing 2 via a protrusion 16 and groove 22 means (see figs.4-5);

wherein the protrusion 16 and groove 22 are annular (see figs. 4-5);

wherein the collar 18 is rotatable about an axis of the holder housing 2 (see col. 3, lines 23-41);

wherein the collar 18 further comprises an interior opening for receiving a needle cannula 28 therein (see figs. 1-4);

wherein the interior opening includes structure 14 for engagement with corresponding mating structure on a needle cannula assembly (see fig.3).

Hollister ('311) discloses a holder assembly, as described above, that fails to explicitly teach an annular skirt.

However, **Hollister ('842)** discloses a holder assembly comprising an annular skirt extending about a receiving port (see fig. 4; col. 4, lines 26-31; col. 6, lines 67-68; col. 7, lines 1-3).

In regards to **claim 1**, since Hollister ('842) teaches a holder assembly wherein addition of an annular skirt 76 allows an annular protrusion 18 on a collar 2 to externally mate with a holder housing 72 (see fig. 4; col. 4, lines 26-31; col. 6, lines 67-68; col. 7, lines 1-3), it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made

to provide the holder assembly of Hollister ('311) with an annular skirt such that the collar is received between the annular skirt and the receiving port of the holder housing as taught by Hollister ('842) in order to allow an annular protrusion on the collar to externally mate with a holder housing.

In regards to **claims 1 & 5-6**, since Hollister ('311) teaches a holder assembly comprising an annular protrusion 16 and a groove 22 for rotatably (i.e. by torque) and frictionally mating the collar 18 against the holder housing 2 such that the safety shield 20 and the collar 18 are axially rotatable with respect to the holder housing 20 about an axis of the holder housing 2 without axial movement of the collar along the axis in order to permit the phlebotomist or nurse to torquably rotate the collar and shield to view the true angle or position of the bevel of the cannula so that the cannula can be more easily and accurately inserted into, for example, the vein of a patient (see col. 1, lines 45-68; col. 2, lines 1-11; col. 3, lines 23-41), it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide the holder assembly of Hollister ('311) as modified by Hollister ('842) above with a collar that includes a protrusion or groove for respectively mating with a groove or protrusion on the holder housing as claimed in order to rotatably (i.e. by torque) and frictionally hold the collar against the holder housing such that a phlebotomist or nurse can torquably rotate the collar and shield to view the true angle or position of the bevel of the cannula so that the cannula can be more easily and accurately inserted into, for example, the vein of a patient.

4. **Claims 3-4** are rejected under 35 U.S.C. 103(a) as obvious over Hollister ('311) in view of Hollister ('842), and further in view of Kobayashi (US 6,695,819).

Hollister ('311) as modified by Hollister ('842) discloses a holder assembly, as described above in claim 1, that fails to explicitly teach a pivot assembly wherein a hanger bar is part of the safety shield and the hook arm is part of collar.

However, **Kobayashi** discloses a holder assembly comprising a hanger bar 78 attached to a safety shield 70 and a hook arm 36 attached to a collar 30 such that the safety shield 70 pivots about the collar 30 (see figs. 2, 4, 8-9 & 12).

Since providing a holder assembly with a pin hinge or a living hinge is an art recognized substitution (see fig. 2A & col. 8, lines 25-35 of US 6,592,556), it would have been obvious to one ordinary skill in the art at the time Applicant's invention was made to provide the holder assembly of Hollister ('311) as modified by Hollister ('842) above with a pivot assembly comprising a hanger bar attached to a safety shield and a hook arm attached a collar as taught by Kobayashi in order to attach the safety shield to the collar such that the safety shield can pivot with respect to the collar for selectively covering a needle cannula.

5. **Claims 3-4** are rejected under 35 U.S.C. 103(a) as obvious over Hollister ('311) in view of Hollister ('842), and further in view of Newby et al. (US 6,440,104).

Hollister ('311) as modified by Hollister ('842) discloses a holder assembly, as described above in claim 1, that fails to explicitly teach a pivot assembly wherein a hanger bar is part of the safety shield and the hook arm is part of collar.

However, **Newby et al.** disclose a holder assembly comprising a hanger bar 182 attached to a safety shield 140 and a hook arm 114 attached to a collar 90 such that the safety shield 140 pivots about the collar 90 (see figs. 1-4).

Since providing a holder assembly with a pin hinge or a living hinge is an art recognized substitution (see fig. 2A & col. 8, lines 25-35 of US 6,592,556), it would have been obvious to one ordinary skill in the art at the time Applicant's invention was made to provide the holder assembly of Hollister ('311) as modified by Hollister ('842) above with a pivot assembly comprising a hanger bar attached to a safety shield and a hook arm attached a collar as taught by Newby et al. in order to attach the safety shield to the collar such that the safety shield can pivot with respect to the collar for selectively covering a needle cannula.

6. **Claim 7** is rejected under 35 U.S.C. 103(a) as obvious over Hollister ('311) in view of Hollister ('842), Newby et al. ('104), and further in view of Alesi et al. (US 2003/0028152).

Hollister ('311) as modified by Hollister ('842) and Newby et al. discloses a holder assembly, as described above in claim 4, that fails to teach a holder assembly wherein the annular skirt on the holder housing substantially encloses an open end of the hook arm.

However, Newby et al. teach that it is known to provide holder assemblies with a hinge comprising a hook arm attached to a collar (see figs. 1-4) and Alesi et al. teach that it is known to provide a living hinge attached to the annular skirt 8 of the holder housing 2 (see abstract; see figs. 7-8; see par 0033); since it is known to substitute living hinges with hinges comprising holes and pegs that securely latch onto the holes for attachment and rotation therethrough as described above, it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide the holder assembly of Hollister ('311) as modified by Hollister ('842) and Newby et al. above with an annular skirt that encloses an open end of the hook arm as claimed in order to achieve a holder assembly wherein, the shield, while only detachably

attachable to the collar, also enjoys the characteristics of a full hinge, notably a secure attachment to the housing and collar (i.e. similar to that of the latching of the full hinge).

7. **Claim 7** is rejected under 35 U.S.C. 103(a) as obvious over Hollister ('311) in view of Hollister ('842), Kobayashi ('819), and further in view of Alesi et al. (US 2003/0028152).

Hollister ('311) as modified by Hollister ('842) and Kobayashi discloses a holder assembly, as described above in claim 4, that fails to teach a holder assembly wherein the annular skirt on the holder housing substantially encloses an open end of the hook arm.

However, Kobayashi teaches that it is known to provide holder assemblies with a hinge comprising a hook arm attached to a collar (see figs. 2, 4, 8-9 & 12) and Alesi et al. teach that it is known to provide a living hinge attached to the annular skirt 8 of the holder housing 2 (see abstract; see figs. 7-8; see par 0033); since it is known to substitute living hinges with hinges comprising holes and pegs that securely latch onto the holes for attachment and rotation therethrough as described above, it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide the holder assembly of Hollister ('311) as modified by Hollister ('842) and Kobayashi above with an annular skirt that encloses an open end of the hook arm as claimed in order to achieve a holder assembly wherein, the shield, while only detachably attachable to the collar, also enjoys the characteristics of a full hinge, notably a secure attachment to the housing and collar (i.e. similar to that of the latching of the full hinge).

8. **Claim 8** is rejected under 35 U.S.C. 103(a) as being unpatentable over Hollister ('311) in view of Hollister ('842), and further in view of Gyure et al. (US 5,681,295).

Hollister ('311) as modified by Hollister ('842) teaches a holder assembly, as described above, that fails to explicitly teach a collar having one or more slits in a rearward portion thereof.

However, **Gyure et al.** disclose a holder assembly comprising a collar having one or more slits in a rearward portion thereof (see figs. 3-4; col. 3, lines 50-67; col. 4, lines 1-27).

Since Gyure et al. teach a holder assembly comprising a collar having one or more slits in a rearward portion thereof so as to provide the collar with some flexibility to allow it to be easily snapped into place (see Gyure et al., col. 4, lines 20-27), it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide the holder assembly of Hollister ('311) as modified by Hollister ('842) with one or more slits as taught by Gyure et al. in order to provide the collar with some flexibility to allow it to be easily snapped into place.

Response to Arguments

9. Applicant's arguments filed November 5, 2008 have been fully considered but they are not persuasive. Applicant argues that there is no suggestion of an annular skirt in Hollister 311 let alone to locate a mounting collar between an annular skirt and a needle receiving port of the holder housing. This argument has been considered but has not been deemed persuasive.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). For example, the Office action does not propose adding an annular skirt to the holder assembly of Hollister ('311) based on

Hollister ('311) alone; moreover, the Office action definitely does not propose locating a mounting collar between an annular skirt and a needle receiving port of the holder housing of Hollister ('311); instead, the Office action proposes locating *an annular skirt* around the collar of Hollister ('311) as taught by Hollister ('842). In fact, Applicant already admits that "Hollister ('311) teaches a collar 918) mounted on the outer surface of the boss (16) (or needle receiving port) of the holder (2)." As such, since Hollister ('311) already teaches a mounting collar surrounding a needle receiving port, why then would the Office action propose locating "a mounting collar" in the device of Hollister ('311)?

With respect to the Applicant's argument that Hollister '842 fails to teach a safety shield and a collar that are axially rotatable with respect to the holder housing about an axis of the holder housing such that the safety shield and the collar can be radially rotated to a desired position around a needle received within the needle receiving port around the axis of the holder housing without axial movement of the collar along the axis. Again, the Examiner notes that the Office action has never claimed nor hinted that Hollister ('842) teaches such an embodiment. Instead, the Office is clear that the teaching of a safety shield and a collar that are axially rotatable with respect to the holder housing about an axis of the holder housing such that the safety shield and the collar can be radially rotated to a desired position around a needle received within the needle receiving port around the axis of the holder housing without axial movement of the collar along the axis can be found in the primary reference of Hollister ('311) (see rejection *supra*).

Moreover, MPEP 2143.01 (VI) prohibits against changing the principle of operation of a reference. As such, the Office action clearly proposes adding an annular skirt to the device of

Hollister ('311) as taught by Hollister ('842) (see rejection *supra*). Since one of the principles of operations of the device of Hollister ('311) involves the use of a rotatable shield/collar assembly without axial movement thereof (see col. 1, lines 45-68; col. 2, lines 1-11), the Office action has further proposed modifying the threads of the annular skirt of Hollister ('842) to include a boss and groove mechanism to allow rotation of the shield/collar assembly without axial movement thereof to facilitate the insertion of the needle into the patient.

In view of the foregoing, the rejections over Hollister ('311) and Hollister ('842) are maintained.

Conclusion

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to RENE TOWA whose telephone number is (571)272-8758. The examiner can normally be reached on M-F, 8:00-16:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/R. T./
Examiner, Art Unit 3736

/Max Hindenburg/
Supervisory Patent Examiner, Art Unit 3736